

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-120

MICROBIOLOGY REVIEW(S)

**REVIEW TO HFD-570
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY TEAM
REVIEW OF NDA**

AUGUST 13, 1996

A. 1. **NDA 20-120** **APPLICANT:** Muro Pharmaceuticals, Inc.
890 East Street,
Tewksbury, MA

2. **PRODUCT NAMES:** Tri-Nasal Spray
Triamcinolone Acetonide

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:**
Non-sterile nasal spray

4. **PHARMACOLOGICAL CATEGORY:**
Treatment of seasonal and perennial allergic rhinitis

B. 1. **DATE OF INITIAL SUBMISSION:** February 12, 1996

2. **ASSIGNED FOR REVIEW:** August 8, 1996

C. **REMARKS:** A request for a microbiological consult was received from the HFD-570 division on August 8, 1996 to evaluate the microbial attributes of the _____ used in manufacturing, the microbial attributes of the bulk and finished product and the *in vitro* biological reactivity of the container.

D. **CONCLUSIONS:** The NDA 20-120 is not recommended for approval from the standpoint of microbiology. Please see Section E for specific comments and the "Microbiologist's Draft of Letter to the Applicant".

/S/ 8/13/96

Patricia F. Hughes, Ph.D.
Review Microbiologist
/S/ - 9/4/96
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cc.: Original NDA 20-120
HFD-160/Consult File
HFD-160/PFHughes
HFD-570/Division File
HFD-570/L.Ng

Drafted by P.F.Hughes/08/13/96
R/D initialed by P. Cooney/08/13/96